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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,763	10/21/2005	John Thomas Brandt	X16303	3837

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,763	BRANDT ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed **10/02/07** presents remarks and arguments to the office action mailed **4/30/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1-4 are pending. Claims 5-14 are cancelled. Claim 2 is amended.

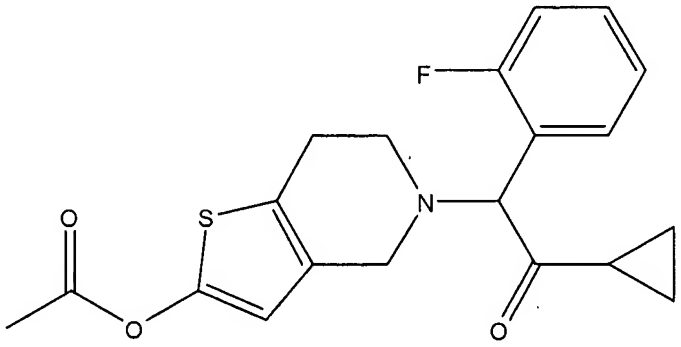
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Asai et al., EP1350511 A1 translated version of WO 02/051412.

Asai et al. teach with regards to the instant claim 1a method of treating cerebrovascular disorder administering a compound of formula I



2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4,5,6,7-tetrahydrothieno[3,2-c]pyridine. It is anticipated that the above drug is administered before angioplastic. Agioplastic is the other name for percutaneous coronary intervention. See page 3, para. 0011.

The drug is also combined with aspirin as required in the instant claim 2. See abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

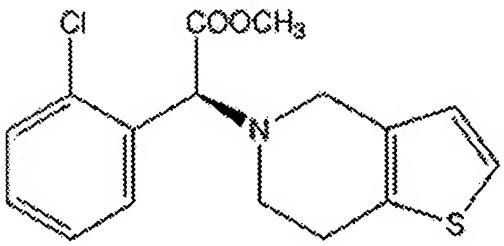
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 e rejected under 35 U.S.C. 103(a) as being unpatentable over Asai et al., EP1350511 A1 translated version of WO 02/051412 in view of Mehta et al. The Lancet vol. 358, 2001 p 527-533 (of record).

Asai is applied here as above. Asai also teaches the drug of compound formula I can be given at appropriate intervals. Asai however, fail to teach the order of administration. Please note claim 4 has the term optionally. Therefore claims 3-4 are obvious of Asai's teaching.

Smith teaches drugs such as aspirin have been used and administered before percutaneous coronary intervention (PCI) (see page 3038) as required by the claims 3-4 in part. The reference also teaches drugs of thienopyrimydine such as clopidogrel



, ticlopidine are used with the PCI procedure.

One of ordinary skill in the art would be motivated to to combine the prior art of reference administer the compound of formula I in its hydrochloric salt in combination with aspirin because the prior art teaches so. As to the order as claimed the Asai's reference suggest giving the drugs at intervals, since both drugs are taught in the art to be used for cerebrovascular disease, it is within the purview of one of ordinary skill in

the art to administer the combination either together, or administer the drug of compound of formula I before agioplastic and then administer aspirin either in combination with the drug of formula I either together or at intervals as sugested by Asai.

Both drugs aspirin and compound I or thionopyridine class of compounds have been used in the treatment of antiplatelet and antithrombotic therapies in coronary.

With regards to the combination with PCI as taught in the Smith et al. reference (see pg. 30380), the technique is used in patients with coronary heart disease with combination of antiplatelet drugs. Thus motivating one of ordinary skill in the art to use in patients with coronary problem which can be done by administering the combination drug prior to the PCI procedure as this helps dissolve blood clot or helps in the blood flow to the brain where poor blood circulation has been diagnosed because it reduces adverse cardiac events.

Although, the reference did not teach the use of a stent with the above compound one of ordinary skill in the art would be motivated to use because the use of a stent in a coronary condition is known, and just like the procedure PCI, stent is a process wherein a tube is passed through the artery for opening of the blocked artery, which is also known as PCI. One of ordinary skill in the art would know that PCI is the procedure that opens the blocked artery, and the use of a stent is to prevent the opening from narrowing which stays in place. Thus after opening of the blocked artery, one of ordinary skill in the art would be motivated to keep the artery from re-narrowing and therefore use a stent.

Mehta et al teach a class of thienopyridine compound clopidrogel is given with aspirin before PCI procedure (see page 527), then after the PCI procedure continued administering the same compound –clopidrogel in combination with aspirin for a duration of 2-4 weeks (see page 528).

Although, the Mehta reference did not teach the compound of formula I, it however, teaches that a particular class the thienopyridine compounds clopidogrel have been used in the order as claimed in claims 3-4. With regards to the said limitation in the instant claim 4, wherein the combination with aspirin is administered 2-30 days prior to performing the surgery is optional and so is the limitation in item c of claim 4.

One of ordinary skill in the art would be motivated to combine the prior art of record, substitute the drug of the cited art clopidogrel to that of the claimed compound as taught by Sugidachi et al. as already discussed above because both drugs are defined as thienopyridine drugs with ADP (adenosine diphosphate) induced platelet aggregation, administer the compound of formula I in the manner that is claimed and taught by Mehta et al. and expect a successful result in doing so.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
11/30/07

Ardin H Marschel 12/9/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER